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APPLICATION NO. FILING DATE FIRST NAMED INVENTOR ATTORNEY DOCKET NO. CONFIRMATION NO. EIP-5784 (1417GP657) 8858 James D. Jacobson 10/040,887 01/07/2002 **EXAMINER** 7590 06/17/2004 HAN, MARK K Francis C. Kowalik, Esq. Corporate Counsel, Law Department PAPER NUMBER **ART UNIT** BAXTER INTERNATIONAL INC. One Baxter Parkway, DF3-2E 3763

DATE MAILED: 06/17/2004

17

Please find below and/or attached an Office communication concerning this application or proceeding.

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Office Action Summary	Application No.	Applicant(s)
	10/040,887	JACOBSON ET AL.
	Examiner	Art Unit
	Mark K Han	3763
The MAILING DATE of this communication appears on the cover sheet with the correspondence address Period for Reply		
A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION. - Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication. - If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely. - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication. - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).		
Status		
1) Responsive to communication(s) filed on 26 February 2004.		
2a) This action is FINAL. 2b) ⊠ This action is non-final.		
3) Since this application is in condition for allowance except for formal matters, prosecution as to the ments is		
closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11, 453 O.G. 213.		
Disposition of Claims		•
4)⊠ Claim(s) <u>1-73</u> is/are pending in the application.		
4a) Of the above claim(s) <u>24-29,32-44,46,51-53,56,60,61 and 68-73</u> is/are withdrawn from consideration.		
5) Claim(s) is/are allowed.		
6)⊠ Claim(s) <u>1-23,30,31,45,47-50,54,55,57-59 and 62-67</u> is/are rejected.		
7) Claim(s) is/are objected to.		
8) Claim(s) are subject to restriction and/or election requirement.		
Application Papers		
9) The specification is objected to by the Examiner.		
10)⊠ The drawing(s) filed on <u>07 January 2002</u> is/are: a)⊠ accepted or b)⊡ objected to by the Examiner.		
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).		
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).		
11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.		
Priority under 35 U.S.C. § 119		
12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).		
a) ☐ All b) ☐ Some * c) ☐ None of:		
1. Certified copies of the priority documents have been received.		
2. Certified copies of the priority documents have been received in Application No		
3. Copies of the certified copies of the priority documents have been received in this National Stage		
application from the International Bureau (PCT Rule 17.2(a)).		
* See the attached detailed Office action for a list of the certified copies not received.		
Attachmont/c\		
Attachment(s) 1) ⊠ Notice of References Cited (PTO-892)	4) \Box Inter	view Summary (PTO-413)
2) D Notice of Draftsperson's Patent Drawing Review (PTO-94	8) Pap	er No(s)/Mail Date
3) Information Disclosure Statement(s) (PTO-1449 or PTO/S Paper No(s)/Mail Date <u>11, 13, 14</u> .	- · · · · · · · · · · · · · · · · · · ·	ce of Informal Patent Application (PTO-152)
U.S. Patent and Trademark Office		
PTOL-326 (Rev. 1-04) Of	ice Action Summary	Part of Paper No./Mail Date 17

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DETAILED ACTION

Election/Restrictions

- 1. Applicant's election without traverse of Species I (claims 1-23, 30, 31, 45, 47-50, 54, 55, 57-59 and 62-67) in the reply filed on 06 October 2003 is acknowledged.
- 2. Claims 24-29, 32-44, 46, 51-53, 56, 60, 61 and 68-73 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected species, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 06 October 2003.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

- (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
- (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.
- 3. Claims 1, 2, 4, 6-14, 16-19, 21, 57-59, 62, 66 and 67 are rejected under 35 U.S.C. 102(e) as being anticipated by U.S. Patent No. 6,723,086 to Bassuk et al (hereinafter "Bassuk").

In reference to claims 1, 16 and 19, Bassuk shows a length of tube 126 and a MEMS element 64. See Figure 3.

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In reference to claims 2, 18 and 57, Bassuk shows a controller 92. See also col. 6, lines 7-14.

In reference to claims 4 and 21, Bassuk shows a flow valve 74, 80 and 86.

In reference to claim 6, the controller is considered to be detachable.

In reference to claim 7, Bassuk shows an information storage. See col. 6, lines 59-62.

In reference to claim 8, Bassuk shows a display 52.

In reference to claims 9 and 59, Bassuk shows a means for network communication 34.

In reference to claim 10, Bassuk shows a means for automated control 92.

In reference to claim 11, the tubing and MEMS element are considered to be disposable.

In reference to claim 12, the controller is considered to be reusable.

In reference to claims 13 and 17, Bassuk shows a power source. See col. 7, lines 64-66

In reference to claim 14, the power source is considered to be disposable.

In reference to claim 58, Bassuk shows an information storage and display.

In reference to claim 62, Bassuk shows a length of tube, a MEMS element, means for connecting and a means for controlling fluid flow.

In reference to claim 66, Bassuk shows a MEMS flow valve 74, 80 and 86.

In reference to claim 67, Bassuk shows a means for supplying power.

4. Claims 1-3, 5-12, 16, 18-20, 22 and 57-59 are rejected under 35 U.S.C. 102(b) as being anticipated by U.S. Patent No. 5,733,256 to Costin.

In reference to claims 1, 16 and 19, Costin shows a length of tube ("infusion conduit") and a MEMS element ("pressure & flow sensors"). See Figure 8 and col. 10, lines 19-22.

In reference to claims 2, 18 and 57, Costin shows a controller ("microprocessor control").

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In reference to claims 3 and 20, Costin shows a flow sensor.

In reference to claims 5 and 22, Costin shows a pressure sensor.

In reference to claim 6, the controller is considered to be detachable.

In reference to claim 7, Costin shows a means for storing information (same means that stores "software").

In reference to claim 8, Costin shows a means for displaying information ("user interface").

In reference to claims 9 and 59, Costin shows a means for network communication.

In reference to claim 10, Costin shows a means for automated control and interrogation.

In reference to claim 11, the tubing and MEMS element are considered to be disposable.

In reference to claim 12, the controller is considered to be reusable.

In reference to claim 58, Costin shows a means for storing and displaying infusion data.

5. Claims 1, 2, 6, 11-19, 23, 30, 31, 45, 47-50, 54, 55, 57, 62, 63 and 67 are rejected under 35 U.S.C. 102(e) as being anticipated by U.S. Patent No. 6,692,481 to Guerrero.

In reference to claims 1, 16 and 19, Guerrero shows a length of tube 90 and a MEMS element 200. See Figure 4. See also col. 4, lines 59-65 and col. 10, lines 35-44.

In reference to claims 2, 18 and 57, Guerrero shows a controller 220.

In reference to claim 6, the controller is considered to be detachable.

In reference to claim 11, the tube and MEMS element are considered to be disposable.

In reference to claim 12, the controller is considered to be reusable.

In reference to claims 13 and 17, Guerrero shows a power source 210.

In reference to claim 14, the power source is considered to be disposable.

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In reference to claims 15 and 23, MEMS element 200 is a pump.

In reference to claim 30, Guerrero shows a tube 90, a MEMS pump element 200 and a power source 210.

In reference to claim 31, the power source is considered to be detachable.

In reference to claims 45, 47-50, 54 and 55, Guerrero discloses the claimed method. See col. 8, line 53 through col. 9, line 30.

In reference to claims 47 and 55, it is considered that discarding the tubing and MEMS pump after use to be inherently part of the method disclosed in the patent.

In reference to claim 54, the step of calibrating is considered to be inherently part of the method disclosed in the patent.

In reference to claim 62, Guerrero shows a length of tube 90, a MEMS element 200, a means for connecting a first end to a container and a means for controlling fluid flow 220.

In reference to claim 63, Guerrero the MEMS element is a pump 200.

In reference to claim 67, Guerrero shows a means for supplying power 210.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

- (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.
- 6. Claims 64 and 65 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bassuk in view of Costin.

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Bassuk shows the claimed invention as shown above except for flow and pressure sensors. Costin suggests pressure and flow sensors in to ensure proper delivery of infusing material as shown above. It would have been obvious to one of ordinary skill in the art to modify the invention of Bassuk to include the pressure and flow sensors of Costin to ensure appropriate delivery of infusing material to the patient.

Response to Arguments

Applicant's arguments, see pp. 15-17, filed 26 February 2004, with respect to the rejection(s) of claim(s) 1, 11, 15, 16, 19, 30, 45, 48, 57 and 62 under 35 U.S.C. §102(b) have been fully considered and are persuasive. Therefore, the rejection has been withdrawn. However, upon further consideration, a new ground(s) of rejection is made in view of Costin, Guerrero and Bassuk.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mark K Han whose telephone number is 703-308-4543. The examiner can normally be reached on Monday to Friday, 9 am to 5:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brian Casler can be reached on 703-308-3552. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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Mark Han
Patent Examiner
Art Unit 3763

mkh June 8, 2004

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